Conscious sedation in interventional radiology: A comparison of Propofol versus Midazolam

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Citation

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Abstract

Most interventional radiological procedures are minimally painful, possibly prolonged and require relative patient immobility, and pose a challenge to the anesthesiologist of providing adequate sedation, immobilization and analgesia without compromising airway or consciousness and ensuring rapid recovery. The study involving 60 patients undergoing interventional radiological procedures compared Propofol and Midazolam with respect to safety and efficacy. Patients in the Midazolam group had more stable hemodynamics and better amnesia, whereas recovery from sedation and discharge from hospital was faster in Propofol group. Level of sedation was satisfactory and incidence of adverse events was minimal (mostly related to pain) in both groups. Both techniques of conscious sedation were satisfactory for interventional radiological procedures with respect to haemodynamics, respiratory parameters, sedation, amnesia, recovery, satisfaction of patient and operator and complications. Propofol though costlier, by ensuring rapid recovery and thus reducing hospital stay may emerge superior and cost effective compared to Midazolam.

INTRODUCTION

The desire to develop minimally invasive therapies gave an impetus to the present upsurge in interventional radiology. These procedures take place in the dark radiology suite under fluoroscopic guidance, most are minimally painful but maybe prolonged and may require relative patient immobility to prevent degradation of the fluoroscopic image. Communication with the patient may have to be maintained throughout the procedure to monitor cerebral function during critical periods or to ask the patient to perform voluntary acts like breath holding. It is also vital to ensure patient's comfort as well as co-operation for better outcome. The anaesthesiologist is thus faced with the task of providing adequate sedation, immobilization, and analgesia without compromising airway or consciousness and ensuring rapid recovery. The aim of this study was to compare two drugs, Midazolam and Propofol, for conscious sedation in interventional radiology in terms of effect on haemodynamics, respiration, amnesia, recovery, operator (interventional radiologist) and patient acceptability and complications.

MATERIALS AND METHODS

After acquiring approval from the hospital ethics committee, 60 patients (ASA grade I/II/III) of either gender in the age group 18-60 years with Glasgow Coma Scale Score of 15/15, scheduled to undergo interventional radiological procedures were included in the study. Patients with anticipated difficult airway, haemodynamic instability, impaired vision; bronchial asthma, IHD, uncompensated hepatic or renal disease and pregnant or lactating patients were excluded from the study by a thorough pre-anaesthetic evaluation.

After procuring a written informed consent, the patients were positioned on the radiology table and intravenous access gained. All the patients were monitored with cardioscope, pulseoximeter and manual blood pressure. A chart containing 18 pictures was shown to the patient for two minutes to check for amnesia later.

All patients received 1μg.kg $^{-1}$ fentanyl i.v. before access area was prepared and draped. The patients were randomly allocated to two groups. Group A patients received 15μg.kg $^{-1}$ Midazolam bolus followed by an infusion @ 0.5μg.kg $^{-1}$ .min $^{-1}$. Those in group B received a bolus of Propofol 0.5mg.kg $^{-1}$ followed by an infusion @ 25μg.kg $^{-1}$ .min $^{-1}$. Infiltration of access area with a local anaesthetic agent was done ten minutes after starting infusion. Infusion was kept constant to maintain Ramsay sedation score $_{1}$ of 3-4. If the patient proceeded to higher level of sedation, infusion was

stopped till patient returned to a sedation score of 4. A bolus dose of fentanyl 25µg was administered as needed for excessive pain. The infusion was stopped at completion of procedure.

The following parameters were noted: Heart rate (HR), blood pressure (BP), oxygen saturation (SpO_2), respiratory rate (RR) and Ramsay sedation score. Ramsay sedation score was assessed at baseline, two, five, ten minutes after starting infusion, then every ten minutes till end of one hour and thereafter every 30 minutes till completion of procedure. After completion of the procedure, Steward's score [2] was assessed at ten minutes to test for speed of immediate recovery. Memory of seeing picture chart and needle prick were assessed at 30 minutes and Post Anaesthesia Discharge Score (PADSS) [3] was assessed at six hours to assess intermediate recovery.

Figure 1

RAMSAY SEDATION SCORE:

Patient anxious agitated or restless	1
Patient co-operative oriented and tranquil	2
Patient asleep responds to commands only	3
Patient asleep responds to gentle shaking, light glabellar tap or loud auditory stimulus	4
Patient asleep, responds to noxious stimuli such as firm nail bed pressure	5
Patient asleep has no response to firm nail-bed pressure other noxious stimuli	6
Inadequate sedation	1
Acceptable sedation	2, 3 or 4
Excessive sedation	5 or 6

STEWARD'S SCORE FOR RECOVERY:

PARAMETER	GRADES
Consciousness	0-4
Airway	0-3
Activity	0-2
Minimum score for recovery	6
Complete recovery	9

POST ANAESTHESIA DISCHARGE SCORING SYSTEM

PARAMETER	POINTS
Vital signs with respect to pre procedure	0-2
Orientation and gait	0-2
Pain, nausea and/or vomiting	0-2
Surgical bleeding	0-2
Intake and output	0-2
Minimum score	0
Maximum score	10
Score sufficient for discharge	9

On complete recovery, patient was asked to state a Visual Analogue Score (VAS) [4] for satisfaction with anaesthetic on a scale from 0-10 (0 being the worst experience ever and 10 being a good experience and would undergo it again if need be).

At completion of procedure, operator was asked to state a VAS [4] from 0-10 (0 –procedure had to be abandoned or general anaesthesia induced due to inappropriate sedation, 10-patient fully co-operative in all respects).

Any complications or undesirable events requiring intervention were looked for looked for and documented, namely:

Respiratory: Oral airway placement, need of jaw thrust, need of mask ventilation, snoring.

Sedation: Nonresponsiveness, loss of co-operation, SpO_2 < 90%, agitation.

Major: Hypotension.

Others: Excessive pain or distress, restlessness or inappropriate movements, any reruns for imaging that were required due to patient's inability to be still, need for induction of general anaesthesia.

The statistical analysis was done using the student t test and z test. @ $p < 0.01$: Highly significant, $ $p < 0.05$: Significant, $p > 0.05$: Not significant

RESULTS

Figure 2

Table 1: Demographic Data

Parameter	Group A		Group B	
	Mean	S.D.	Mean	S.D.
Age (years)	40.5	14.68	39.3	13.24
Weight (kgs)	55.10	10.85	55.47	11.55
Duration (hours)	0.89	0.45	0.97	0.5573
Sex Male (number)	16		22	
Female(number)	14		8	

Figure 3

Table 2: Interventional Procedures

Procedures	Group A	Group B
	Number (%)	Number (%)
Lower Limb Angiography	7(23.33)	3(10.00)
Lower Limb Angioplasty	4(13.33)	2(06.67)
Upper Limb Angioplasty	0(00.00)	2(06.67)
Four Vessel Digital Subtraction Angiography (DSA)	5(16.67)	12(40.00)
Splenic Aneurysm Embolisation	1(03.33)	2(06.67)
Aortogram	2(06.67)	2(06.67)
Renal Angiography	1(03.33)	0(00.00)
Renal Artery Stenting	2(06.67)	2(06.67)
Internal Carotid Artery Stenting	0(00.00)	1(03.33)
Coeliac Axis DSA	0(00.00)	1(03.33)
Paraspinal Arterio Venous Malformation Embolisation	1(03.33)	0(00.00)
Lower Limb Venography	0(00.00)	1(03.33)
Percutaneous Nephrostomy	3(10.00)	2(06.67)
Percutaneous Tranhepatic Biliary Drainage	3(10.00)	2(06.67)
Common Bile Duct Stenting	1(03.33)	0(00.00)

Figure 4

Table 3: Haemodynamics (Blood Pressure And Heart Rate)

Time Interval	Group A (mm Hg)	Group B (mm Hg)	P value	Group A (rate/min)	Group B (rate/min)	P value
Minutes	Mean ± S.D.	Mean ± S.D.		Mean ±S.D.	Mean ± S.D.	
Pre op	134.60±18.78	131.10±16.70	0.4491#	89.03±22.75	85.62 ± 16.13	0.5053#
0	134.13±19.01	130.20±17.73	0.4106#	85.43±14.12	84.50 ± 16.42	0.8142#
2	131.50±18.59	126.20±16.93	0.2530#	83.50±13.42	82.20 ± 15.98	0.7342#
5	126.40±17.89	121.00±16.28	0.2264#	82.17±13.04	80.70 ± 15.46	0.6927#
10	118.43±25.40	115.73±13.92	0.6116#	81.97±12.70	84.27 ± 16.38	0.5457#
20	122.40±16.52	114.00±12.85	0.0320$	80.03±13.40	81.30 ± 15.89	0.7397#
30	122.33±15.73	114.13±12.69	0.0302$	78.93±12.76	79.93 ± 16.62	0.7947#
40	123.64±15.80	116.07±12.47	0.0439$	79.39±12.53	79.56 ± 16.12	0.9653#
50	123.39±15.61	115.58±13.15	0.0405$	79.39±12.42	80.50 ± 14.26	0.7493#
60	123.79±16.08	116.33±13.36	0.0556#	79.95±10.85	77.72 ± 11.39	0.4416#
90	129.60±17.02	120.71±14.11	0.0317$	82.40 ± 9.23	78.14 ± 12.66	0.1421#
120	120.00± 0.00	111.20± 8.79	-- #	95.00 ± --	83.20 ± 0.55	-- #

NOTE: @ (p < 0.01) Highly significant; $ (p < 0.05) Significant; # (p > 0.05) Not significant' (p-values by students t-test)

Table 3 shows that the mean blood pressure values decreased after starting infusion and the decrease persisted for 30 minutes in group A and 20 minutes in group B. Statistical significance in difference in decrease in BP was noted during the interval between 20-50 minutes after starting infusion and then again at 90 minutes interval. There was no incidence of clinically significant hypotension in either group.

Figure 5

Table 4: Respiratory Parameters (Mean Respiratory Rate And Oxygen Saturation)

Time intervals	Group A (rate/min)	Group B (rate/min)	p-value	Group A (% O_2Sat)	Group B (% O_2Sat)	P value
Minutes	Mean±S.D.	Mean±S.D.		Mean ±S.D.	Mean±S.D.	
Pre-op	17.20 ± 3.24	18.41±3.55	0.1721#	99.67 ± 0.71	99.59 ± 0.78	0.6778 #
0	17.03 ± 3.07	18.37±3.20	0.1049#	99.77 ± 0.57	99.47 ± 0.86	0.1165 #
2	16.60 ± 2.82	17.40±2.98	0.2901#	99.77 ± 0.57	99.47 ± 1.07	0.1816 #
5	16.20 ± 2.33	16.73±3.67	0.5037#	99.73 ± 0.69	99.27 ± 1.17	0.0654 #
10	16.67 ± 3.29	17.80±3.66	0.2126#	99.77 ± 0.57	98.87 ± 1.55	.0041@
20	16.27 ± 3.03	16.67±3.59	0.6428#	99.77± 0.57	99.13 ± 1.28	0.0161 $
30	16.07 ±3.14	16.30±3.30	0.7801#	99.80 ± 0.48	99.23 ± 1.17	0.0169 $
40	15.96 ± 2.71	16.52±3.76	0.5150#	99.79 ± 0.50	99.37 ± 0.79	0.0182 $
50	15.83 ± 2.21	16.54±3.62	0.3595#	99.74 ± 0.62	99.33 ± 0.92	0.0492 $
60	16.00 ± 1.73	16.22±3.15	0.7364#	99.84 ± 0.50	99.28 ± 0.89	.0038@
90	15.60 ± 1.43	16.79±3.89	0.1223#	100.0 ± 0.00	99.57 ± 0.65	.0006@
120	16.00 ± --	17.20±3.35	-- #	100 ± --	99.60 ± 0.55	-- #

NOTE: @ (p < 0.01) Highly significant; $ (p < 0.05) Significant; # (p > 0.05) Not significant' (p-values by students t-test)

Table 4 shows that the respiratory rate is well maintained in both groups throughout the procedure. It also shows that there is statistically significant difference in oxygen saturation between the two groups, with the value being lower in group B. However there is no incidence of desaturation.

Figure 6

Table 5: Amnesia

Parameter	Group A		Group B		P value
	Yes (%)	No (%)	Yes (%)	No (%)	
Amnesia of prick	12 (40)	18 (60)	11 (37)	19 (63)	0.3953 #
Amnesia of seeing chart	15 (50)	15 (50)	3 (10)	27 (90)	0.0004 @

NOTE: @ (p < 0.01) Highly significant ; $ (p < 0.05) Significant ; # (p > 0.05) Not significant' (p-values by Z-test for proportions)

Table 5 shows that 90% patients in group B had recall of seeing chart pictures as against only 50% in group A. Amnesia to prick of needle was 40% in group A and 37% in group B.

Figure 7

Table 6: Sedation Score

Time interval	Group A	Group B	P value
	Mean ± S.D.	Mean ± S.D.	
0	1.90 ± 0.31	1.82 ± 0.39	0.3884 #
2	2.20 ± 0.61	2.20 ± 0.61	--- #
5	2.57 ± 0.57	2.60 ± 0.72	0.8435 #
10	2.80 ± 0.66	2.87 ± 0.68	0.7026 #
20	2.90 ± 0.84	3.03 ± 0.76	0.5242 #
30	2.90 ± 0.80	3.07 ± 0.78	0.4196 #
40	2.86 ± 0.59	3.04 ± 0.81	0.3289 #
50	2.91 ± 0.51	3.00 ± 0.88	0.6434 #
60	2.95 ± 0.52	2.67 ± 1.24	0.2576 #
90	3.10 ± 0.57	2.86 ± 0.86	0.2035 #
120	2.00 ± --	2.40 ± 0.55	-- #

NOTE: @ (p < 0.01) Highly significant; $ (p < 0.05) Significant; # (p > 0.05) Not significant' (p-values by students t-test)

Table 6 shows the mean sedation scores were around three starting at ten minutes after commencing infusion in both groups and the score was maintained at around three throughout the procedure.

Figure 8

Table 7: Visual Analogue Score (Operator And Patient)

VAS	Operators			Patients		
	Group A (%)	Group B (%)	P value	Group A (%)	Group B (%)	P value
4	0 (0)	0 (0)	#	0 (0)	1 (3)	0.1566 #
6	0 (0)	1 (3)	#	2 (7)	0 (0)	#
7	1 (3)	0 (0)	0.1566 #	3 (10)	4 (13)	0.0752 #
8	9 (30)	7 (23)	0.1566 #	10 (33)	5 (17)	0.3438 #
9	5 (17)	3 (10)	0.2797 #	4 (13)	6 (20)	0.0680 #
10	15 (50)	19 (63)	0.2238 #	11 (37)	14 (47)	0.2442 #

NOTE: @ (p < 0.01) Highly significant; $ (p < 0.05) Significant; # (p > 0.05) Not significant' (p-values by Z-test for proportions)

Table 7 shows that 97% operators in group A and 96% operators in group B had visual analogue score (VAS) of 8 and above and 83% patients in group A and 84 % patients in group B had VAS of 8 and above.

Figure 9

Table 8: Recovery Score At 10 Minutes After Completion Of Procedure

Score	Group A (%)	Group B (%)	P value
5	0 (0)	0 (0)	--- #
6	4 (13)	2 (7)	0.1947 #
7	9 (30)	2 (7)	0.0098 @
8	11 (37)	9 (30)	0.2919 #
9	6 (20)	17 (57)	0.0017 @

NOTE: '@ (p < 0.01) Highly significant; $ (p < 0.05) Significant; # (p > 0.05) Not significant' (p-values by Z-test for proportions)

Table 8 shows that 20% of patients in group A as against 57% patients in group B had complete recovery. But all patients in both groups fulfilled the minimum criteria for recovery i.e. a minimum score of 6.

Figure 10

Table 9: Discharge Score

Discharge score at 6 hrs	Group A (%)	Group B (%)	P value
8	0 (0)	1 (3)	0.1566 #
9	0 (0)	0 (0)	---
10	30 (100)	29 (97)	0.1566 #

NOTE: '@ (p < 0.01) Highly significant; $ (p < 0.05) Significant; # (p > 0.05) Not significant' (p-values by Z-test for proportions)

Table 9 shows that 100% patients in Group A and 97% patients in group B had post anaesthesia discharge score of 10 at six hours.

Figure 11

Table 10: Adverse Effects

Adverse effects	Group A (%)	Group B (%)	p-value
Pain	10 (33)	11 (37)	0.3933 #
Movement	6 (20)	7 (23)	0.3770 #
Fentanyl	7 (23)	6 (20)	0.3770 #
Snoring	3 (10)	1 (3)	0.1503 #

NOTE: '@ (p < 0.01) Highly significant; $ (p < 0.05) Significant; # (p > 0.05) Not significant' (p-values by Z-test for proportions)

Pain and pain related movement, which were tackled with bolus doses of fentanyl, were the most frequent undesirable events followed by snoring, which interfered with fluoroscopic imaging.

DISCUSSION

Many of the interventional radiological procedures do not require general anaesthesia and it is usually sufficient to provide light sedation with vigilant monitoring. The goals of conscious sedation include amnesia, anxiolysis and analgesia so that the patient is comfortable, co-operative, relatively immobile and willing, if necessary, to return for a repeat procedure.

To achieve appropriate level of sedation a variety of anaesthetic agents have been used. But the search for better drugs, which will maintain haemodynamic stability and ensure rapid recovery, continues.

As per recent literature and pharmacological reviews [4,5,6,7,8,9] Midazolam and Propofol fulfill the criteria for day care procedures in interventional radiology. Therefore, in our study, we have chosen these two drugs, Midazolam and Propofol in dosages suited to obtain a level of mild sedation in which the patient is relatively immobile, calm, tranquil and easily arousable.

With Propofol there was a stastistically significant greater fall in systolic blood pressure compared to that with Midazolam. Fall in blood pressure is commonly seen with old age, poor physical status, and concomitant use of opioids.

Till Wehrmann and colleagues [5] compared the efficacy and safety of intravenous Propofol v/s Midazolam sedation during routine Endoscopic Retrograde Cholangio Pancreatography (ERCP). They observed a significantly greater decrease in mean blood pressure with Propofol than with Midazolam.

Respiratory rate was well maintained in both groups during the procedure. There was a statistically significant fall in oxygen saturation in group B. However there was no incidence of clinically significant desaturation in either group.

M.Jung and colleagues [6] in their study to compare the quality of sedation under Propofol and Midazolam in patients undergoing Endoscopic Retrograde Cholangio Pancreatography found a drop in oxygen saturation (Propofol – 4%, Midazolam – 2%) in both groups. The difference was not significant.

In our study patients were shown a chart of 18 pictures. They were asked for recall of the pictures at 30 minutes after stopping sedative infusion. 15 (50%) patients in group A as against 27 (90%) in group B were clearly able to recall these while the rest were amnesic to seeing them. This indicates better amnesia by Midazolam and was statistically significant.

12 (40%) patients in group A and 11 (37%) patients in group B were amnesic to needle prick whereas the rest had memory of the prick. Though the difference between the two was not statistically significant, on the whole, it indicates

poor amnesia to noxious stimuli.

E.Wilson and colleagues [10] concluded that early post operative amnesia was significantly greater with Midazolam.

The degree of sedation was assessed using the Ramsay sedation score. The quality of sedation was found to be comparable between the two groups with the score being maintained around three (which was considered adequate seadation for the procedures) in both groups. There was no statistically significant difference between the two groups.

M.R.Polster and co workers [11] concluded that Midazolam and Propofol had similar sedative effects both immediately after bolus doses and after one hour continuous infusion of the drugs.

We found that the VAS as stated by both patient and operator were comparable in both groups indicating that both drugs afford good patient comfort and compliance and favourable operating conditions and there was no statistically significant difference between the two groups. (Percentage of operators with VAS of 8 and above - 97% in group A v/s 96% in group B. Percentage of patients with VAS of 8 and above - 83% in group A v/s 84% in group B.)

P.H.Manninen and co workers [4] have found that the satisfaction of the anaesthetic techniques as evaluated by the neuroradiologist as well as by the patient showed no difference between Propofol and Midazolam.

We assessed immediate and intermediate recovery in our study by assessing Steward's recovery score and PADSS respectively.

We found that group B had statistically significant greater percentage of patients(50%) with complete recovery as compared to group A(20%) indicating that recovery was faster with Propofol than with Midazolam. However the intermediate recovery as assessed by the PADSS was good with both drugs (100% in group A v/s 97% in group B), with most patients being fit for discharge at the end of six hours.

M.Jung and co workers [6] concluded that according to Steward score and trieger test the patients given Propofol woke up earlier than those given Midazolam.

We found that the incidence of side effects was minimal. Pain and pain related events were the most significant complaints by both operator and patient. Both drugs, Midazolam and Propofol, were comparable in this respect.

Pirjo H Manninen and co-workers [4] found that the incidence of anaesthetic related complications was not great and there was no difference between the two groups.

CONCLUSION

In conclusion, we found that both techniques of conscious sedation, Midazolam and Propofol; with Fentanyl were satisfactory for interventional radiological procedures with respect to haemodynamics, respiratory parameters, sedation, amnesia, recovery, satisfaction of patient and operator and complications. Improving analgesia could possibly improve patient co-opeartion and thus operator comfort. Propofol though costlier, by ensuring rapid recovery and thus reducing hospital stay may emerge superior and cost effective compared to Midazolam.

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